

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

IAN WALLACE,

Plaintiff,

vs.

PHARMA MEDICA RESEARCH, INC.; TRIS
PHARMA, INC.; ROXANE
LABORATORIES, INC.; HIKMA LABS,
INC.; and WEST-WARD COLUMBUS, INC.,

Defendants.

Cause No. 4:18-cv-01859-PLC

**DEFENDANT TRIS PHARMA, INC.'S MEMORANDUM OF LAW IN SUPPORT OF
MOTION FOR SUMMARY JUDGMENT**

COMES NOW Defendant, Tris Pharma, Inc. ("Tris"), by and through their undersigned counsel, and for their Memorandum of Law in Support of Motion for Summary Judgment in accordance with Federal Rule of Civil Procedure 56 and Local Rule 4.01 states to the Court as follows:

INTRODUCTION

On December 9, 2019, Plaintiff Ian Wallace filed his Second Amended Complaint against Tris, Hikma Labs, Inc., Pharma Medica Research, Inc. ("Pharma") and others for his injuries allegedly sustained in contracting Hepatitis C during a blood drawing processes at Pharma's St. Charles, Missouri facility while participating in medical studies. See Second Amended Complaint attached hereto as Exhibit A.

Defendant Tris contracted with Pharma to perform an open-label, randomized, two-way crossover, multiple-dose pivotal study to evaluate the relative bioavailability of the test product of codeine polstirex, chlorpheniramine polistirex, and psudoephedrine polistirex extended-release oral suspension compared to an equivalent dose of the reference products, Tuzistra XR Extended-

release oral suspension and pseudoephedrine hydrochloride IR oral solution, under steady-state conditions in healthy adult subjects. See Informed Consent Form attached hereto as Exhibit B. This medical study was designed to test a new medication designed, manufactured, supplied and/or created by Defendant Tris. See Exhibit A.

Pharma operated this study out of its screening clinic and Phase I clinic in St. Charles, Missouri. See Exhibit A. This study included multiple blood draws. See Exhibit A. Plaintiff was a voluntary participant in this study. See Exhibit B.

At the time of this study, Tris had an agreement with Pharma where Pharma and Tris specifically agreed that Pharma was not an agent of Tris. See Master Service Agreement attached hereto as Exhibit B. Paragraph 11 of the Master Service Agreement reads as follows:

11. Independent Contractor Status

11.1 It is understood and agreed that CRO (Pharma) is an independent contractor and will not have any right to any of Tris benefits, not for any purposes be deemed or intended to be an employee of Tris. CRO agrees to make any payments or withdrawing required by the Internal Revenue Code of 1986, as amended, the regulations promulgated thereunder, social security and any related statutes or regulations.

11.2 It is further understood that CRO is not an agent of Tris and Tris is not an agent of CRO and neither party is authorized to bind the other party with respect to any third party. See Master Service Agreement attached hereto as Exhibit B.

In Count II of Plaintiff's Second Amended Complaint, Plaintiff alleged Pharma was negligent in allegedly using a needle in the blood drawing process which was unsanitary or unsterile thereby causing Plaintiff to contract Hepatitis C. See Exhibit A. In Court II, Plaintiff sought to impute Pharma's alleged negligence to Tris on the theory of agency. See Exhibit A. Additionally, in Count V, Plaintiff sought recovery based on a theory of res ipsa loquitur and, more specifically, that contracting Hepatitis C from a blood draw did not ordinarily happen in the

absence of negligence. See Exhibit A. Plaintiff sought to impute Pharma's alleged negligence to Tris on the theory of agency. See Exhibit A.

Counts II and V of the Second Amended Complaint should be dismissed against Tris as Pharma was not an agent of Tris and therefore, any claims of negligence of Pharma cannot be imputed to Tris. Despite months of discovery and numerous depositions, Plaintiff has not identified any evidence which established that Pharma was an agent of Tris. Thus, any alleged negligence of Pharma cannot be imputed to Tris and Tris was entitled to judgment as a matter of law.

STANDARD OF REVIEW

Summary judgment is proper, "if the pleadings, depositions, answers to interrogatories, and admission of file, if any, show that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 332 (1986). If a party who has had adequate time for discovery failed to make a sufficient showing to establish the existence of any element of his case, summary judgment is proper. *Id.* at 322.

Here, Plaintiff had sufficient time to complete discovery and produce any evidence of agency between Pharma and Tris. However, as Pharma was not an agent of Tris, no such evidence existed and summary judgment was proper here.

ARGUMENT

COUNT II AND V SHOULD BE DISMISSED AGAINST TRIS AS THE ALLEGED NEGLIGENCE WAS COMMITTED BY PHARMA AND PHARMA WAS NOT AN AGENT OF TRIS

"There is no presumption of agency and the burden of establishing it is on the party asserting it." *Martin v. Mercantile Tr. Co.*, 293 S.W.2d 319, 325 (Mo. 1956). Here, Plaintiff had

no evidence to support his allegations that Pharma was an agent of Tris. In fact, the evidence refuted any agency relationship. Thus, Plaintiff failed to meet his burden.

In order to establish agency between two corporations, Plaintiff must establish each element set forth in *State ex rel. Ford Motor Co. v. Bacon*, 63 S.W.3d 641, 642 (Mo. banc. 2002) and *Blanks v. Fluor Corp.*, 450 S.W.3d 308, 383 (Mo. App. E.D. 2014). The three essential elements were: 1) that an agent holds a power to alter legal relations between the principal and a third party; 2) that an agent is a fiduciary with respect to matters within the scope of the agency; and 3) that a principal has the right to control the conduct of the agent with respect to matters entrusted to the agent. *Bacon*, 63 S.W.3d at 642. The absence of any of these three characteristics defeated the purported agency relationship. *Id.*

In the case at bar, Plaintiff failed to allege the three required elements. He based his claim of agency solely on one element – control by one corporation over the other. Even if the evidence supported such a finding, meeting just one element was insufficient to establish agency between Pharma and Tris. Further, Plaintiff had no evidence to meet the remaining two elements required to establish agency.

In *Bacon*, the Court found an agency relationship did not exist between Ford Motor Company and Ford Motor Credit Company. 63 S.W.2d at 644. There, Plaintiff sought venue in the Circuit Court of Greene County, Missouri in cases against Ford Motor Company. *Id.* at 642. However, Ford Motor Company did not maintain any offices in Greene County and the cause of action did not occur in Greene County. *Id.* Plaintiff argued venue was proper because Ford Motor Credit Company, Ford's wholly-owned subsidiary, maintained an office in Greene County, Ford Motor Credit Company was an agent of Ford Motor Company, thus venue was proper. *Id.*

However, the Court disagreed finding Ford Motor Credit Company was not an agent of Ford Motor Company. *Id.*

The court analyzed that, “[a]gency is the fiduciary relationship which results from the manifestation of consent of one person to another that the other shall act on his behalf and subject to his control, and consent by the other. *Bacon*, 63 S.W.2d at 642. The *Bacon* Court then adopted a test for determining when an agency relationship exists between two corporations: 1) that an agent holds a power to alter legal relations between the principal and a third party; 2) that an agent is a fiduciary with respect to matters within the scope of the agency; and 3) that a principal has the right to control the conduct of the agent with respect to matters entrusted to the agent. *Id.*

In analyzing the relationship between Ford Motor Company and Ford Motor Credit Company, the court found agency had not been established because Plaintiff failed to present evidence that Ford Motor Credit Company had any power to alter the legal relations between Ford Motor Company and a third party. *Bacon*, S.W.2d at 642. This failure to meet the first element of the three-part test was enough for the Court to find agency was not established. *Id.*

The agency test set forth in *Bacon* was later analyzed and adopted by the Missouri Court of Appeals for the Eastern District of Missouri in 2014 in *Blanks v. Fluor Corp.*, 450 S.W.3d 308 (Mo. App. E.D. 2014).

In *Blanks*, the Court found the plaintiffs failed to prove their theory of agency. 450 S.W.3d at 333. There, Plaintiffs, the families of children who suffered lead poisoning while living in Herculaneum, Missouri sued the partners of The Doe Run Company Partnership which owned and operated a lead smelter from 1986 to 1994. *Id.* at 323. The lawsuit was filed against three of the partners of Doe run Company Partnership including Flor Corporation, A.T. Massey Coal Company and Doe Run Investment Holding Company. *Id.* at 333. The families sued each defendant

separately seeking to hold each one liable on each defendant's negligence as well as the partnership's negligence. *Id.* The families filed an additional claim against Fluor Corporation seeking to hold it liable because of its "complete and pervasive control of the subsidiaries that were partners in the Doe Run Partnership." *Id.* at 333-334.

After losing at trial, Defendants appealed. One argument was that the theory of liability against Fluor Corporations was not valid under traditional agency and the Court of Appeals agreed. *Blanks*, 450 S.W.3d at 383. The Court noted the families sought to hold Fluor liable under traditional agency principles, "merely because of its dominations of and control of its subsidiaries. This is insufficient." *Id.* The Court held that in order to prevail on the issue of agency between two corporations, a plaintiff must meet all three elements but there only one element was met. *Id.*

1. Plaintiff failed to plead the essential three elements for an agency theory.

Here, Plaintiff sought to impute liability to Tris for Pharma's alleged negligence in drawing Plaintiff's blood under traditional agency principles. In the Second Amended Complaint, Plaintiff did not allege that Tris was directly negligent or directly performed the blood draws. Instead, Plaintiff alleged:

9. ... TPI controlled the actions of PMR or had the right to control the actions of PMR in said study. Such control enabled TPI to visit PMR's facility to assure compliance with TPI's instructions, policies, rules, protocols, and guidelines; monitor PMR's conduct; request all information from PMR during the study; require reports from PMR; require audits; require quality assurance and quality control systems; require specific testing procedures including blood draws; regulate meal and sleep times of study participants; and all other restrictions set

forth in the aforesaid study guidelines. Defendant also require PMR carry insurance for the study participants.

10. That at all relevant times, PMR was acting as the agent for TPI in the scope of its employment by TPI for the aforesaid study. As such, TPI is responsible for PMR's actions during the study.

See Exhibit A.

Here, as in *Bacon* and *Blanks*, Plaintiff sought to establish agency between Pharma and Tris based on the traditional principles of agency and based solely on Tris' alleged control over the Pharma related to the medical study. As in both *Bacon* and *Blanks*, Plaintiff only alleged one element of the three-part test: domination and control. Here, Plaintiff did not allege that Pharma had any power to alter legal relations between it and third parties. Further Plaintiff did not allege that either party was a fiduciary with respect to matters within the scope of their agency. As in *Blanks* and *Banks*, the failure to establish all three elements was fatal.

Plaintiff not only failed to establish any evidence to prove all three elements, he failed to even allege two of the required three elements. As such, the pleading alone was deficient and Plaintiff failed to state a valid claim against Tris for negligence or res ipsa loquitur based on agency. As in *Bacon* and *Blanks*, this Court should find that Plaintiff failed to present a valid claim of agency such that Pharma's alleged negligence cannot be imputed to Tris.

2. Plaintiff failed to meet his burden as he cannot show any evidence of the required three elements of agency.

Here, Plaintiff failed to meet each of the *Bacon* elements. The first requirement necessary to establish agency between two corporations was evidence that one corporation had the power to alter legal relations between Pharma and any third party. *Bacon*, S.W.2d at 642. Plaintiff had no evidence that Pharma had the power to alter legal relations between Tris and any third party. In

fact, the Master Services Agreement that both Pharma and Tris agreed to, specifically showed that Pharma was not an agent of Tris and that Pharma was not authorized to bind Tris with respect to any third party. See Exhibit B. As such, Plaintiff failed to meet part one of the *Bacon* test.

Second, Plaintiff failed to meet the second element as Plaintiff failed to produce any evidence that Pharma was a fiduciary of Tris within the scope of their relationship. As such, Plaintiff failed to meet part two of the *Bacon* Test.

Finally, Plaintiff cannot support the only *Bacon* element he had alleged – that Tris controlled Pharma in its medical study. To the contrary, the testimony of Dr. Shabaz Khan and Dr. Heather Jordan both supported a finding that there was no control by Tris over Pharma. Both Dr. Khan and Dr. Jordan testified that the written protocol (study guidelines) governed every aspect of the study including the drawing of blood. See Deposition of Dr. Shabaz Khan, P. 102, L. 1-4, attached hereto as Exhibit C; and Deposition of Dr. Heather Jordan, P. 23, L. 5-9, attached hereto as Exhibit D. There is no evidence that Tris had any authority over how Pharma conducted the study.

Dr. Khan testified that Pharma medical studies were conducted pursuant to a protocol. See Exhibit C, P. 53, L. 6-8. The testimony of Dr. Khan confirmed that the written protocol which governed how the medical study was to be conducted was researched and written by a Pharma research/writing team. See Exhibit C, P. 61, L. 8-9; 19-20. All of these team members were employed by Pharma. *Id.* at P. 61, L. 19-10. The protocol governed everything ranging from what medication to administer to the time a participant's blood was to be drawn and tested to determine how the blood was to be drawn. See Exhibit D, P 22, L. 9-17. The guidelines required to be included in the protocol were determined by the FDA. See Exhibit C, P. 57, L. 6-7. The sponsor, here Tris, did not have input in creating the guidelines for a study. See Exhibit C, P. 57, L. 3-6.

Here, as the medical study was conducted pursuant to a protocol that was prepared by Pharma, with guidelines from the FDA, and no input from Tris, there was no evidence that Tris controlled any aspect of the study, including the blood draws done by Pharma. Additionally, the Master Services Agreement between Pharma and Tris specifically stated that Pharma was hired as an independent contractor. See Exhibit B.

The undisputed facts in this case establish Tris had no control or authority regarding how the study procedures or requirements would be conducted including the procedure for drawing blood. These decisions were made either by the FDA or Pharma itself.

Tris was entitled to summary judgment on Counts II and V as there was no evidence to support any of the elements set forth in *Bacon*.

CONCLUSION

Defendant Tris was entitled to summary judgment on Count II and V because Plaintiff failed to plead each and every element required to establish agency between two corporations pursuant to *Bacon*.

Additionally, Tris was also entitled to summary judgment on Counts II and V because there was no evidence to support any of the elements set forth in *Bacon*. Plaintiff failed to produce any evidence that Pharma had any power to alter the legal relationships between Tris and any third party. Plaintiff also failed to produce any evidence that Pharma was a fiduciary with respect to the agreement between Pharma and Tris. Finally, the undisputed facts in this case firmly established that Tris had no control or authority over Pharma or how it conducted the medical study.

Defendant incorporated herein by reference their Statement of Undisputed Facts in Support of Motion for Summary Judgment.

WHEREFORE, Defendant Tris Pharma, Inc., prays this Court grant its Motion for Summary Judgment as the Counts II and V of the Second amended Complaint and for such further and other relief as this Court deems just and proper.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was electronically filed and served to counsel via the Court's e-filing system on this 12th day of October, 2020, addressed to the following attorney(s) of record:

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